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EXAMINER

ARNOLD, ERNST V

ART UNIT PAPER NUMBER

1616

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/758,513

Applicant(s)

LEMAIRE, MARC

Examiner

Ernst V. Arnold

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-66 is/are pending in the application.
- 4a) Of the above claim(s) 16-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/21/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

The Examiner acknowledges receipt of remarks filed by the Applicant on 2/21/2006. Applicant has cancelled claims 16-41 and added new claims 42-66. The Examiner has carefully considered Applicants arguments but has not found them to be persuasive. A new ground of rejection has been made. This action is non-final. Claims 42-66 are pending.

#### **Response to arguments:**

1. As stated above, Applicant has cancelled claims 16-41 thus rendering the Examiner's claims rejections under 35 USC 112, first paragraph moot. The rejection is withdrawn.
2. For the same reasons, the 35 USC 102(a) rejection over Homi et al. is withdrawn.
3. For the same reasons, the 35 USC 102(b) rejection over Bracken is withdrawn.
4. For the same reasons, the 35 USC 102(b) rejection over Mondain-Monval is withdrawn.
5. For the same reasons, the 35 USC 102(b) rejection over Jevtovic-Todorovic et al. is withdrawn.
6. For the same reasons, the 35 USC 102(b) rejection over Vanderipe is withdrawn.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 64 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner if Applicant intended "an inhalable medicinal" of instant claim 64 to depend from "an inhalable medicinal" of instant claim 63 or as drawn to method claim 62. Applicant is requested to clarify the claim dependency. Claim 66 is rejected as indefinite because it depends from an indefinite claim. Since claim 64 is drawn to a composition, then the Examiner will examine the claim as if it depended from composition claim 63.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 63-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Mondain-Monval (US 4,820,258).

Instant claim 63 is drawn to an inhalable medicinal composition containing a therapeutically-effective amount of nitrous oxide and xenon for treating or minimizing post-ischemic brain cell deterioration in said human.

Mondain-Monval disclose a gaseous mixture comprising oxygen, nitrous oxide, and an optional inert gas, such as nitrogen or xenon, to be administered by inhalation to a patient (See: Abstract; Column 1, lines 59-62; column 2, lines 10-14 and lines 22-25;

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and claims 4 and 5). The volume of nitrous oxide is between 50 and 80% by volume and at least about 20% by volume of oxygen Column 1, lines 66-68 and column 2, lines 1-2). The gaseous mixture can be in the form of a ternary mixture consisting of oxygen, nitrous oxide and the complement to 100% by volume by an inert gas selected from nitrogen, argon, krypton, xenon and helium (Column 2, lines 10-14 and claims 2-5). For example, if a gaseous composition were comprised of 50% nitrous oxide and 20% oxygen then the complement in xenon would be 30%. Thus instant claims 63-66 are anticipated.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

### ***Claim Rejections - 35 USC § 102***

Claims 63-66 are rejected under 35 U.S.C. 102(a) as being anticipated by Homi et al. (Anesthesiology 2003, 99, 876-881).

Homi et al. disclose that the effect of xenon on both functional and histological outcome after reversible focal cerebral ischemia is unknown and that they hypothesized

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that xenon would attenuate histologic injury and improve functional neurologic outcome after transient middle cerebral artery occlusion in the mouse (Page 876, upper right column). Homi et al. disclose the neuroprotective effect of xenon administration during transient middle cerebral artery occlusion in mice (Abstract). (Please note: The Examiner interprets this to be a blockage simulating an ischemic stroke and therefore the disclosure of Homi et al. reads upon a method of treating or minimizing post-ischemic brain cell deterioration.) Homi et al. provide gaseous compositions and methods of administering the gas to a subject (See: Materials and Methods page 876). Homi et al. temporarily occluded the right carotid artery with a microsurgical aneurysm clip (Page 877, left column, second paragraph).

Homi et al. administered three gas mixtures to mice subjected to 60 minutes of middle cerebral artery occlusion: 1) 70% xenon and 30% oxygen; 2) 70% nitrous oxide and 30% oxygen; and 3) 35% xenon and 35% nitrous oxide and 30% oxygen (Page 877, left column, last paragraph; page 878, under results; Table 2, page 878 upper right and corner and Figure 1, page 879, for example). The Examiner interprets about 75% of instant claim 23 to mean  $75\% \pm 7.5\%$  which provides a range of 67.5% to 82.5% nitrous oxide. The amount of nitrous oxide used in the disclosure of Homi et al. (70%) is within the scope of the instant invention and would therefore constitute an effective amount and anticipate instant claims 63-66.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Homi et al. (Anesthesiology 2003, 99, 876-881) in view of Mondain-Monval (US 4,820,258)

The references of Homi et al. and Mondain-Monval are described above and that discussion is hereby incorporated by reference.

Homi et al. do not expressly disclose a method of treating or minimizing post-ischemic brain cell deterioration in humans wherein the method comprises adding oxygen and nitrogen to said medicinal composition and the gaseous nitrous oxide and xenon is placed in a pressurized gas container.

Mondain-Monval provide a general teaching on the administration of a gaseous mixture comprising at least about 50% by volume of nitrous oxide to a patient (a human) by inhalation (Claim 1). Mondain-Monval teach the addition of an inert gas to the nitrous oxide and point out xenon (Claim 5). Mondain-Monval claim the method of administration of a gaseous mixture wherein the gaseous mixture contains from about 50 to 80% by volume nitrous oxide, at least 20% by volume oxygen (Claims 2 and 3). Further, Mondain-Monval teach a gaseous mixture comprising oxygen, nitrous oxide and an inert gas (Claim 4). The inert gas is selected from the group consisting of

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nitrogen, argon, krypton, xenon and helium (Claim 5). It is the Examiner's position that one of ordinary skill in the art has the ability to select the appropriate inert gas(es) for inclusion in the gaseous mixture. The Examiner interprets about 75% of instant claim 50 to mean  $75\% \pm 7.5\%$  which provides a range of 67.5% to 82.5% nitrous oxide.

Therefore, the disclosure of Mondain-Monval is within the scope of the instant invention and would constitute an effective amount. The Examiner interprets that inhalation means that the components to be inhaled are in gaseous form and any subject inhaling the gaseous mixture would receive any benefit from doing so. Mondain-Monval disclose that the gaseous mixtures can be prepackaged under pressures compatible with maintaining the mixtures in gaseous form (Column 2, lines 15-17). The Examiner interprets this to mean the gaseous mixture in a pressurized gas container. Gas bottles and gas cylinders are synonymous and are known in the art as typical storage containers for pressurized gases.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the gaseous composition, contained in pressurized gas containers, of Mondain-Monval in the method of Homi et al. for treating or minimizing post-ischemic brain cell deterioration in humans and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Homi et al. teach that mice exposed to transient focal cerebral ischemia had reduced infarct size and improved neurologic outcome as a result of xenon anesthesia administered during the ischemic insult but that the method requires considerable



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extension in other species to confirm the potential clinical relevance of the results (Page 880, bottom left column and upper right column). It is the Examiner's position that "other species" and "clinical relevance" clearly point towards studies in humans.


From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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